

Board of Chiropractic Examiners

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**Board of Chiropractic Examiners****Final Statement of Reasons**

Hearing Date: October 21, 2004

Subject Matter of Proposed Regulations: Manipulation Under Anesthesia (MUA)

Sections Affected: Adopt Section 361 of Division 4 of Title 16

Updated Information

The Board, in response to the comment received, modified the proposed language by excluding a licensed medical or osteopathic physician certified in anesthesiology through the American Board of Medical Specialties to administer the anesthetic, sedative or other drug during the MUA procedure. Accredited hospitals where the MUA procedure is performed will determine who administers the anesthesia.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Business Impact

This section will not have a significant adverse economic impact on businesses.

Consideration of Alternatives

No alternative that was considered would be either more effective than or equally as effective as and less burdensome to affected private persons than the proposed regulation.

Objections or Recommendations/Responses

The following comments were made regarding the proposed regulatory change:

Written Comments

By letter dated October 19, 2004, William E. Barnaby of Barnaby Governmental Relations, submitted a statement of concerns on behalf of the California Society of Anesthesiologists (CSA) regarding the following issues:

- There is not an adequate scientific or factual basis for a regulation that implies that MUA is within acceptable standards of practice.

Response

The California Code of Regulations, Division 4 of Title 16, does not require that chiropractic practices be evidence-based. This comment is not relevant to the proposed amendment, and, thus not within the scope of rulemaking.

- A regulation, which assumes the legality of MUA in chiropractic practice and thus implicitly authorizes it, cannot be reconciled with the Chiropractic Initiative Act. Anesthesiologists must be assured that their participation in MUA procedures does not raise liability concerns because of the application of the Chiropractic Act.

Response

The Chiropractic Initiative Act authorizes chiropractors within their scope of practice to perform spinal manipulation, stretching and mobilization procedures. The Act does not imply that these procedures are prohibited under the use of anesthesia. Furthermore, the Board has modified the language to rely on the accredited hospitals to make the determination as to who administers the anesthesia during the MUA procedure. The modification to the language will alleviate any liability concerns relating to the Act.

- The Board's Notice, in the section titled "Informative Digest/Policy Statement Overview", cites Section 302 of the Board's present regulations, which refers to authorization to manipulate and adjust the spinal column and other joints, and states "*there is no prohibition to the use of anesthesia to complete these manipulations*" (emphasis added). The Chiropractic Initiative Act which defines and regulates the chiropractic scope of practice, authorizes licensees to practice chiropractic as defined therein, but expressly excludes and thus prohibits "the use of any drug or medicine nor or hereafter included in material medica."

Response

The purpose of the proposed regulation is to ensure patient protection during treatment of MUA and licensees performing the procedure. According to the proposed language, it does not authorize a chiropractor to administer anesthesia. Accredited hospitals will determine who administers the anesthesia.

- A letter submitted by The Doctors Company endorses and supports the written comments submitted by Mr. Barnaby on behalf of CSA regarding the proposed regulation dealing with MUA.

Response

Refer to the response to the California Society of Anesthesiologists.

The California Orthopaedic Association expressed the following concerns:

- Comments that chiropractors should only be allowed to perform manipulation under anesthesia if all other treatments have been exhausted and not as the initial or routine course of treatment. In addition, the regulation should be clarified to specify that the medical physician evaluating the patient prior to the manipulation be limited to board certified orthopaedic surgeons, neurosurgeons, or physiatrists whose practice involves the treatment of spine problems.

Response

The Board does not agree that chiropractors should only be allowed to perform MUA after all other treatments have been exhausted. The Board is relying on a medical or osteopathic physician to make the appropriate recommendation for MUA treatment. In addition, the regulation provides that the recommending physician has knowledge of the MUA procedure and understand the options for the patient.

The California Medical Association expressed the following concerns:

- MUA is outside of the chiropractic scope of practice and raises serious questions concerning hospital privileges and malpractice liability that make such procedures untenable.

Response

MUA is increasing within the chiropractic profession and the procedure is being performed by a growing number of licensees. Currently there is no regulation that prohibits chiropractors from manipulating under anesthesia. Therefore, to ensure public safety, the proposed regulation requires that the MUA procedure be performed at a hospital that is licensed by the California Department of Health Services and certified

by either Medicare or the Joint Commission on Accreditation of Healthcare Organizations, or is performed in an Ambulatory Surgery Center which meets the requirements of Health and Safety Code Section 1248-1248.5. In addition, the proposed language requires licensees to carry malpractice insurance with an endorsement for MUA.

The Osteopathic Physicians & Surgeons of California (OPSC) expressed the following concerns:

- It is not clear whether the 32 hours required for training is sufficient
- There is no criteria indicated for training standardization
- Requirements for re-training are not clearly delineated
- Does not specify the qualifications of an MD/DO “familiar” with MUA
- Hospital licensure does not include the American Osteopathic Association’s Healthcare Facilities Accreditation Program, nor is AOA certification of anesthesiologists noted
- A patient should not be exposed to the potential dangers associated with MUA if the procedure is performed by anyone other than a licensed physician

Response

Currently Section 302, Practice of Chiropractic, allows chiropractors to manipulate and adjust the spinal column and other joints of the human body with no prohibition to the use of anesthesia during these manipulations. The purpose of this regulation is to specify the educational requirements for licensees who perform MUA procedures and the conditions under which the procedures may be performed. The Board feels that the concerns expressed by OPSC are addressed within the proposed regulation in its entirety.

Public Hearing Comments

- Kristine Schultz, California Chiropractic Association, thanked the Board for its effort in implementing this regulation. However, she commented that the Board does not have the authority to define the scope of practice of other professions.

Response

The Board does not feel that the proposed language defines the scope of practice of other professions. This comment is not relevant to the proposed amendment, and, thus not within the scope of rulemaking.

- Melissa Cortez, representing California Association of Nurse Anesthetists (CANA), expressed her concerns regarding eliminating the Certified Registered Nurse Anesthetists (CRNA) in the proposed regulation as one of the providers of anesthesia during the MUA procedure.

Response

As mentioned, the Board has modified the language to rely on the accredited hospitals to make the determination on who administers the anesthesia during the MUA procedure.

- Patrick Shannon, representing the CANA, commented on the issues previously raised by Ms. Cortez.

Response

Please refer to the response previously addressed to Ms. Cortez.

- Kathleen Creason, representing the Osteopathic Physicians & Surgeons of California (OPSSC), reiterated the concerns as previously submitted in the letter dated October 20, 2004 discussed under written comments.

Response

Please refer to the response previously addressed to Ms. Creason under written comments.

- Ed Cremata, D.C. expressed his concerns on issues addressed by the California Association of Nurse Anesthetists and the Osteopathic Physicians & Surgeons of California during public comments. He elaborated on those issues and made suggestions to the Board on how to resolve them.

Response

The Board feels that the issues raised by the CANA and OPSC have been addressed during public comment. Therefore, this comment is not relevant to the proposed amendment, and, thus not within the scope of rulemaking.

- Rick Skala, D.C. commented on healthcare companies dictating what practice is appropriate for other professions.

Response

The Board feels that this comment is not relevant to the proposed amendment, and, thus not within the scope of rulemaking.

The modified language was made available to the public from March 25, 2005 through April 9, 2005.

Written Comment on Modified Language

William E. Barnaby, Inc. submitted comments on behalf of the CSA concerning the following:

- The proposed language allows a procedure that requires the use of drugs that is precluded by Section 7 of the Chiropractic Act. In addition, the proposed modification eliminates the requirement that anesthesia must be administered by a physician. The change could be read to suggest that chiropractors may administer the drugs used in the MUA procedure, compounding the violation of law, which is the precept of this regulation.

Response

The Board disagrees with this comment. Section 302, Practice of Chiropractic clearly defines the chiropractic scope of practice and does not imply that manipulation is prohibited under anesthesia. In addition, the proposed language does not suggest that chiropractors may administer the drugs used during the MUA procedure. The language was modified to allow the facility where the MUA procedure is performed to determine who administers the anesthesia. The anesthesiologist will be responsible for monitoring the patient throughout the procedure.